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DATE: Thursday, August 05, 2004

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|--------------------------|-----------------|--|------------------|
| | | <i>DB=USPT,EPAB,JPAB,DWPI,TDBD; PLUR=YES; OP=OR</i> | |
| <input type="checkbox"/> | L5 | (peg) same (polylact\$ or polyglycol\$ or polyvinyl) same emulsion | 81 |
| <input type="checkbox"/> | L4 | (peg) same (polylact\$ or polyglycol\$ or polyvinyl) same micelle | 51 |
| <input type="checkbox"/> | L3 | (peg) same (polylact\$ or polyglycol\$ or polyvinyl) same lipid | 89 |
| <input type="checkbox"/> | L2 | (peg) same (polylact\$ or polyglycol\$ or polyvinyl) same phospholipid | 32 |
| <input type="checkbox"/> | L1 | peg same (polylact\$ or polyglycol\$ or polyvinyl) | 1967 |

END OF SEARCH HISTORY

1. Document ID: US 6716412 B2

Apr 6, 1904

DOCUMENT-IDENTIFIER: US 6716412 B2

US-CL-CURRENT: 424/9.52; 424/450, 424/9.5, 424/9.51, 514/44, 600/437, 604/21

[illegible]

Feb 24, 2004

US-CL-CURRENT: 424/451; 252/363.5, 424/458, 424/464, 424/469, 424/470, 424/478,
424/490

| Full | Title | Citation | From | Review | Classification | Date | Reference | System D |
|------|-------|----------|------|--------|----------------|------|-----------|----------|
|------|-------|----------|------|--------|----------------|------|-----------|----------|

☐ 3. Document ID: US 6569452 B1

L2: Entry 3 of 32

File: USPT

May 27, 2003

US-PAT-NO: 6569452

DOCUMENT-IDENTIFIER: US 6569452 B1

**** See image for Certificate of Correction ****

TITLE: Pharmaceutical formulations in hydroxypropylmethylcellulose capsules

DATE-ISSUED: May 27, 2003

INVENTOR-INFORMATION:

| NAME | CITY | STATE | ZIP CODE | COUNTRY |
|---------------------|-------|-------|----------|---------|
| Civaroli; Paola | Milan | | | IT |
| Muggetti; Lorena | Milan | | | IT |
| Martini; Alessandro | Milan | | | IT |

US-CL-CURRENT: 424/451; 424/452, 424/462, 424/484, 424/486, 514/283, 514/772,
514/778, 514/962

| Full | Title | Citation | From | Review | Classification | Date | Reference | System D |
|------|-------|----------|------|--------|----------------|------|-----------|----------|
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☐ 4. Document ID: US 6558698 B2

L2: Entry 4 of 32

File: USPT

May 6, 2003

US-PAT-NO: 6558698

DOCUMENT-IDENTIFIER: US 6558698 B2

TITLE: Microencapsulated bioactive agents and method of making

DATE-ISSUED: May 6, 2003

INVENTOR-INFORMATION:

| NAME | CITY | STATE | ZIP CODE | COUNTRY |
|---------------------|---------|-------|----------|---------|
| Morrison; Dennis R. | Kemah | TX | | |
| Mosier; Benjamin | Houston | TX | | |

US-CL-CURRENT: 424/451; 264/4.33, 424/450, 424/452, 424/489, 424/490, 427/202.33

| Full | Title | Citation | From | Review | Classification | Date | Reference | System D |
|------|-------|----------|------|--------|----------------|------|-----------|----------|
|------|-------|----------|------|--------|----------------|------|-----------|----------|

☐ 5. Document ID: US 6548047 B1

L2: Entry 5 of 32

File: USPT

April 10, 2003

DOCUMENT-IDENTIFIER: US 6548047 B1

DATE-ISSUED: April 15, 2003

INVENTOR- INFORMATION:

| NAME | CITY | STATE | ZIP CODE | COUNTRY |
|----------------|--------|-------|----------|---------|
| Unger; Evan C. | Tucson | AZ | | |

US-CL-CURRENT: 424/9.51; 424/450, 424/9.4, 424/9.5, 424/9.52

[illegible]

6. Document ID: US 6517866 B1

L2: Entry 6 of 32

File: USPT

FEB 11, 2003

DOCUMENT-IDENTIFIER: US 6517866 B1

TITLE: Sertraline salts and sustained-release dosage forms of sertraline

DATE-ISSUED: February 11, 2003

INVENTOR - INFORMATION:

| NAME | CITY | STATE | ZIP CODE | COUNTRY |
|------------------------|-------------|-------|----------|---------|
| Am Ende; Mary Tanya | Griswold | CT | | |
| Curatolo; William John | Niantic | CT | | |
| Friedman; Hylar Lewis | Brattleboro | VT | | |
| Friesen; Dwayne Thomas | Bend | OR | | |
| Herbig; Scott Max | East Lyme | CT | | |
| Shankar; Ravi Mysore | Groton | CT | | |
| West; James Blair | Bend | OR | | |

US-CL-CURRENT: 424/457; 424/458, 424/463, 424/468, 424/469, 424/473, 424/477,
424/484, 424/490

[illegible]

7. Document ID: US 6499984 B1

L2: Entry 7 of 32

File: USPT

Dec 30, 2002

DOCUMENT-IDENTIFIER: US 6499984 B1

TITLE: Continuous production of pharmaceutical granulation

DATE-ISSUED: December 31, 2002

INVENTOR-INFORMATION:

| NAME | CITY | STATE | ZIP CODE | COUNTRY |
|-------------------------|---------------|-------|----------|---------|
| Ghebre-Sellassie; Isaac | Morris Plains | NJ | | |
| Mollan, Jr.; Matthew J. | Succasunna | NJ | | |
| Pathak; Nitin | Succasunna | NJ | | |
| Lodaya; Mayur | Succasunna | NJ | | |
| Fessehaie; Mebrahtu | New York | NY | | |

US-CL-CURRENT: 425/135; 241/152.2, 241/260.1, 264/117, 425/174.8E, 425/202,
425/204, 425/222, 425/224

| Full | Citation | From | Review | Classification | Date | Reference | Image De |
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☐ 8. Document ID: US 6485528 B1

L2: Entry 8 of 32

File: USPT

Nov 26, 2002

US-PAT-NO: 6485528

DOCUMENT-IDENTIFIER: US 6485528 B1

TITLE: Agents for treating keratin fibers

DATE-ISSUED: November 26, 2002

INVENTOR-INFORMATION:

| NAME | CITY | STATE | ZIP CODE | COUNTRY |
|------------------|-------------|-------|----------|---------|
| Bartels; Holger | Hamburg | | | DE |
| Wolff; Wolfgang | Bargteheide | | | DE |
| Hoepfner; Stefan | Hamburg | | | DE |
| Rohweder; Sandra | Hamburg | | | DE |

US-CL-CURRENT: 8/405; 8/406, 8/409, 8/410, 8/411

| Full | Citation | From | Review | Classification | Date | Reference | Image De |
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☐ 9. Document ID: US 6479540 B1

L2: Entry 9 of 32

File: USPT

Nov 12, 2002

US-PAT-NO: 6479540

DOCUMENT-IDENTIFIER: US 6479540 B1

**** See image for Certificate of Correction ****

TITLE: Compositions of tocol-soluble therapeutics

DATE-ISSUED: November 12, 2002

INVENTOR-INFORMATION:

| NAME | CITY | STATE | ZIP CODE | COUNTRY |
|-------------------------------|-------------|-------|----------|---------|
| Constantinides; Panayiotis P. | Gurnee | IL | | |
| Lambert; Karel J. | Woodinville | WA | | |
| Tustian; Alexander K. | Bothell | WA | | |
| Nienstedt; Andrew M. | Seattle | WA | | |

US-CL-CURRENT: 514/458; 424/400, 514/937, 514/938, 549/407

| Full | Citation | Front | Review | Classification | Date | Reference | | | | Sum D |
|------|----------|-------|--------|----------------|------|-----------|--|--|--|-------|
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☐ 10. Document ID: US 6444660 B1

L2: Entry 10 of 32

File: USPT

Sep 11, 2002

US-PAT-NO: 6444660

DOCUMENT-IDENTIFIER: US 6444660 B1

TITLE: Lipid soluble steroid prodrugs

DATE-ISSUED: September 3, 2002

INVENTOR-INFORMATION:

| NAME | CITY | STATE | ZIP CODE | COUNTRY |
|----------------|--------|-------|----------|---------|
| Unger; Evan C. | Tucson | AZ | | |
| Shen; DeKang | Tucson | AZ | | |

US-CL-CURRENT: 514/180

| Full | Citation | Front | Review | Classification | Date | Reference | | | | Sum D |
|------|----------|-------|--------|----------------|------|-----------|--|--|--|-------|
|------|----------|-------|--------|----------------|------|-----------|--|--|--|-------|

☐ 11. Document ID: US 6391343 B1

L2: Entry 11 of 32

File: USPT

May 21, 2002

US-PAT-NO: 6391343

DOCUMENT-IDENTIFIER: US 6391343 B1

TITLE: Fibrinogen-coated particles for therapeutic use

DATE-ISSUED: May 21, 2002

INVENTOR-INFORMATION:

| NAME | CITY | STATE | ZIP CODE | COUNTRY |
|--------------------|-------------|-------|----------|---------|
| Yen; Richard C. K. | Yorba Linda | CA | | |

US-CL-CURRENT: 424/491; 424/78.06, 427/2.14, 514/2, 514/834, 514/937, 514/954,
516/77

| Full | Citation | Front | Review | Classification | Date | Reference | | | | Sum D |
|------|----------|-------|--------|----------------|------|-----------|--|--|--|-------|
|------|----------|-------|--------|----------------|------|-----------|--|--|--|-------|

☐ 12. Document ID: US 6368620 B2

L2: Entry 12 of 32

File: USPT

Apr 9, 2002

US-PAT-NO: 6368620

DOCUMENT-IDENTIFIER: US 6368620 B2

TITLE: Formulations comprising lipid-regulating agents

DATE-ISSUED: April 9, 2002

INVENTOR-INFORMATION:

| NAME | CITY | STATE | ZIP CODE | COUNTRY |
|--------------|---------------|-------|----------|---------|
| Liu; Rong | Gurnee | IL | | |
| Pan; Qinghai | Lake Bluff | IL | | |
| Lee; Dennis | Highland Park | IL | | |

US-CL-CURRENT: 424/451; 424/456, 424/489, 424/490

| | | | | | | | | | |
|------|----------|--------|--------|----------------|------|-----------|----------|----------|--------|
| Full | Citation | Claims | Review | Classification | Date | Reference | Examiner | Comments | Form D |
|------|----------|--------|--------|----------------|------|-----------|----------|----------|--------|

☐ 13. Document ID: US 6348214 B1

L2: Entry 13 of 32

File: USPT

Feb 19, 2002

US-PAT-NO: 6348214

DOCUMENT-IDENTIFIER: US 6348214 B1

TITLE: Materials and methods for making improved liposome compositions

DATE-ISSUED: February 19, 2002

INVENTOR-INFORMATION:

| NAME | CITY | STATE | ZIP CODE | COUNTRY |
|--------------------|-----------------|-------|----------|---------|
| Onyuksel; Hayat | Western Springs | IL | | |
| Rubinstein; Israel | Highland Park | IL | | |

US-CL-CURRENT: 424/450; 264/4.1, 264/4.3, 264/4.6, 514/2, 514/21

| | | | | | | | | | |
|------|----------|--------|--------|----------------|------|-----------|----------|----------|--------|
| Full | Citation | Claims | Review | Classification | Date | Reference | Examiner | Comments | Form D |
|------|----------|--------|--------|----------------|------|-----------|----------|----------|--------|

☐ 14. Document ID: US 6322810 B1

L2: Entry 14 of 32

File: USPT

Nov 21, 2001

US-PAT-NO: 6322810

DOCUMENT-IDENTIFIER: US 6322810 B1

TITLE: Materials and methods for making improved micelle compositions

DATE-ISSUED: November 27, 2001

INVENTOR-INFORMATION:

| NAME | CITY | STATE | ZIP CODE | COUNTY |
|-----------------------|-----------------|-------|----------|--------|
| Alkan-Onyuksel; Hayat | Western Springs | IL | 60558 | |
| Rubinstein; Israel | Highland Park | IL | 60035 | |

US-CL-CURRENT: 424/450; 424/1.21, 424/812, 424/9.321, 424/9.51, 424/94.3,
428/402.2, 436/829, 514/21, 514/937

| File | Citation | From | Review | Classification | Date | Reference | | | | Final Dis |
|------|----------|------|--------|----------------|------|-----------|--|--|--|-----------|
|------|----------|------|--------|----------------|------|-----------|--|--|--|-----------|

☐ 15. Document ID: US 6217886 B1

L2: Entry 15 of 32

File: USPT

Apr 11 2001

US-PAT-NO: 6217886

DOCUMENT-IDENTIFIER: US 6217886 B1

TITLE: Materials and methods for making improved micelle compositions

DATE-ISSUED: April 17, 2001

INVENTOR-INFORMATION:

| NAME | CITY | STATE | ZIP CODE | COUNTY |
|--------------------|-----------------|-------|----------|--------|
| Onyuksel; Hayat | Western Springs | IL | | |
| Rubinstein; Israel | Highland Park | IL | | |

US-CL-CURRENT: 424/401; 264/4.1, 264/4.3, 264/4.6, 424/1.21, 424/450, 424/9.321,
424/9.51, 514/2, 514/21, 514/937

| File | Citation | From | Review | Classification | Date | Reference | | | | Final Dis |
|------|----------|------|--------|----------------|------|-----------|--|--|--|-----------|
|------|----------|------|--------|----------------|------|-----------|--|--|--|-----------|

☐ 16. Document ID: US 6197333 B1

L2: Entry 16 of 32

File: USPT

Mar 6 2001

US-PAT-NO: 6197333

DOCUMENT-IDENTIFIER: US 6197333 B1

TITLE: Materials and methods for making improved liposome compositions

DATE-ISSUED: March 6, 2001

INVENTOR-INFORMATION:

| NAME | CITY | STATE | ZIP CODE | COUNTY |
|--------------------|-----------------|-------|----------|--------|
| Onyuksel; Hayat | Western Springs | IL | | |
| Rubinstein; Israel | Highland Park | IL | | |

US-CL-CURRENT: 424/450; 424/401

17. Document ID: US 6190691 B1

Feb 27, 2001

DOCUMENT-IDENTIFIER: US 6190691 B1

DATE-ISSUED: February 20, 2001

| NAME | CITY | STATE | ZIP CODE | COUNTRY |
|-------------------|------------|-------|----------|---------|
| Mak; Vivien H. W. | Menlo Park | CA | | |

[illegible]

☐ 13. Document ID: US 6123923 A

Sep 20 2000

**** See image for Certificate of Correction ****

DATE-ISSUED: September 26, 2000

| NAME | CITY | STATE | ZIP CODE | COUNTRY |
|----------------|--------|-------|----------|---------|
| Unger; Evan C. | Tucson | AZ | | |
| Wu; Yungiu | Tucson | AZ | | |

[illegible]

19. Document ID: US 6099864 A

Aug 2000

DOCUMENT-IDENTIFIER: US 6099864 A

DATE-ISSUED: August 8, 2000

| NAME | CITY | STATE | ZIP CODE | COUNTRY |
|---------------------|---------|-------|----------|---------|
| Morrison; Dennis R. | Kemah | TX | | |
| Mosier; Benjamin | Houston | TX | | |

US-CL-CURRENT: 424/489; 264/4.1, 264/4.3, 264/4.32, 264/4.33, 424/423, 424/420,
428/402.2, 428/402.21, 514/951

[illegible]

L2: Entry 20 of 32

File: USPT

Jul 18, 2000

DOCUMENT IDENTIFIER: US 6090800 A

DATE-ISSUED: July 18, 2000

| NAME | CITY | STATE | ZIP CODE | COUNTRY |
|----------------|--------|-------|----------|---------|
| Unger; Evan C. | Tucson | AZ | | |
| Shen; DeKang | Tucson | AZ | | |

US-CL--CURRENT: 514/180; 552/574

[illegible]

L2: Entry 21 of 32

File: USPT

Jun 6, 2000

DOCUMENT-IDENTIFIER: US 6071494 A

DATE-ISSUED: June 6, 2000

| NAME | CITY | STATE | ZIP CODE | COUNTRY |
|----------------|--------|-------|----------|---------|
| Unger, Evan C. | Tucson | AZ | | |

[illegible]

L2: Entry 22 of 32

File: USPT

000 5, 1999

DOCUMENT-IDENTIFIER: US 5962477 A

**** See page for Certificate of Correction ****

DATE-ISSUED: October 5, 1999

| NAME | CITY | STATE | ZIP CODE | COUNTRY |
|-------------|------------|-------|----------|---------|
| Mak; Vivian | Menlo Park | CA | | |

[illegible]

L2: Entry 23 of 32

File: USPT

Dec 8 1998

DOCUMENT-IDENTIFIER: US 5846517 A

**** See Image for Certificate of Correction ****

DATE-ISSUED: December 8, 1998

| NAME | CITY | STATE | ZIP CODE | COUNTRY |
|----------------|--------|-------|----------|---------|
| Unger, Evan C. | Tucson | AZ | | |

| Citation | Search | Review | Classification | Date | Reference | Final Disposition |
|----------|--------|--------|----------------|------|-----------|-------------------|
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L2: Entry 24 of 32

File: USPT

Dec 1 1998

http://westlrs:9000/bin/gate.exe?f=TOC&state=qq65om.3&ref=2&dbname=USPT,EP/AE/JPA... 8/5/04

DATE-ISSUED: December 1, 1998

| NAME | CITY | STATE | ZIP CODE | COUNTRY |
|--------------------------------|---------------|-------|----------|---------|
| Woodle; Martin C. | Menlo Park | CA | | |
| Bakker-Woudenberg; Irma A.J.M. | Bergschenhoek | | | NET |
| Martin; Francis J. | San Francisco | CA | | |

US-CL-CURRENT: 424/450; 514/62, 514/78

| Class | Topic | Review | Classification | Date | Reference |
|-------|-------|--------|----------------|------|-----------|
| | | | | | |

25. Document ID: US 5827531 A

L2: Entry 25 of 32

File: USPT

Oct. 27, 1998

US-PAT-NO: 5827531

DOCUMENT-IDENTIFIER: US 5827531 A

TITLE: Microcapsules and methods for making

DATE-ISSUED: October 27, 1998

INVENTOR- INFORMATION:

| NAME | CITY | STATE | ZIP CODE | COUNTRY |
|---------------------|---------|-------|----------|---------|
| Morrison; Dennis R. | Kemah | TX | | |
| Mosier; Benjamin | Houston | TX | | |

US-CL-CURRENT: 424/450; 264/4.32, 264/4.33, 424/451, 424/489, 424/490, 407/413.3,
428/402.21, 428/402.24

[illegible]

25. Document ID: US 5512268 A

L2: Entry 26 of 32

File: USPT

Apr 30, 1996

US-PAT-NO: 5512268

DOCUMENT-IDENTIFIER: US 5512268 A

TITLE: Polymeric shells for medical imaging prepared from synthetic polymers, and methods for the use thereof

DATE-ISSUED: April 30, 1996

INVENTOR - INFORMATION:

| NAME | CITY | STATE | ZIP CODE | COUNTRY |
|----------------------|-------------------|-------|----------|---------|
| Grinstaff; Mark W. | Pasadena | CA | | |
| Desai; Neil P. | Los Angeles | CA | | |
| Suslick; Kenneth S. | Champaign | IL | | |
| Soon-Shiong; Patrick | Los Angeles | CA | | |
| Sandford; Paul A. | Los Angeles | CA | | |
| Merideth; Noma R. | Pacific Palisades | CA | | |

US-CL-CURRENT: 424/9.322; 424/9.42, 424/9.5, 424/9.52, 436/173

| | | | | | | | | | |
|--------|----------|-------|--------|----------------|------|-----------|--------|--------|--------|
| Patent | Citation | Entry | Review | Classification | Date | Reference | Patent | Patent | Patent |
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17. Document ID: US 5508021 A

L2: Entry 27 of 32

File: USPT

Apr 16, 1996

US-PAT-NO: 5508021

DOCUMENT-IDENTIFIER: US 5508021 A

TITLE: Non-fluorinated polymeric shells for medical imaging

DATE-ISSUED: April 16, 1996

INVENTOR INFORMATION:

| NAME | CITY | STATE | ZIP CODE | COUNTRY |
|----------------------|-------------------|-------|----------|---------|
| Grinstaff; Mark W. | Pasadena | CA | | |
| Desai; Neil P. | Los Angeles | CA | | |
| Suslick; Kenneth S. | Champaign | IL | | |
| Soon-Shiong; Patrick | Los Angeles | CA | | |
| Sandford; Paul A. | Los Angeles | CA | | |
| Merideth; Noma R. | Pacific Palisades | CA | | |

US-CL-CURRENT: 424/9.322; 424/9.42, 424/9.5, 436/173

| | | | | | | | | | |
|--------|----------|-------|--------|----------------|------|-----------|--------|--------|--------|
| Patent | Citation | Entry | Review | Classification | Date | Reference | Patent | Patent | Patent |
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18. Document ID: US 5505932 A

L2: Entry 28 of 32

File: USPT

Apr 9, 1996

US-PAT-NO: 5505932

DOCUMENT-IDENTIFIER: US 5505932 A

TITLE: Method for the preparation of fluorocarbon-containing polymeric shells for medical imaging

DATE-ISSUED: April 9, 1996

INVENTOR INFORMATION:

| NAME | CITY | STATE | ZIP CODE | COUNTRY |
|----------------------|-------------------|-------|----------|---------|
| Grinstaff; Mark W. | Pasadena | CA | | |
| Desai; Neil P. | Los Angeles | CA | | |
| Suslick; Kenneth S. | Champaign | IL | | |
| Soon-Shiong; Patrick | Los Angeles | CA | | |
| Sandford; Paul A. | Los Angeles | CA | | |
| Merideth; Noma R. | Pacific Palisades | CA | | |

US-CL-CURRENT: 424/9.3, 424/9.322, 424/9.34, 424/9.37, 424/9.5, 424/9.52, 436/173

| Pat. No. | Citation | Front | Review | Classification | Date | Reference | Pat. No. | Pat. No. | Pat. No. |
|----------|----------|-------|--------|----------------|------|-----------|----------|----------|----------|
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11 29. Document ID: US 5376369 A

L2: Entry 29 of 32

File: USPT

Dec 27, 1994

US-PAT-NO: 5376369

DOCUMENT-IDENTIFIER: US 5376369 A

TITLE: Vaccine adjuvant

DATE-ISSUED: December 27, 1994

INVENTOR-INFORMATION:

| NAME | CITY | STATE | ZIP CODE | COUNTRY |
|---------------------|-----------------|-------|----------|---------|
| Allison; Anthony C. | Belmont | CA | | |
| Byars; Noelene E. | Sunnyvale | CA | | |
| Fu; Cherng-Chyi | Saratoga | CA | | |
| Lidgate; Deborah M. | Los Altos | CA | | |
| Felgner; Philip L. | Rancho Santa Fe | CA | | |
| Foster; Linda C. | Sunnyvale | CA | | |
| Lee; William A. | Los Altos | CA | | |

US-CL-CURRENT: 424/278.1, 424/279.1, 424/283.1, 436/543, 514/8, 514/885, 530/322, 530/806, 530/815

| Pat. No. | Citation | Front | Review | Classification | Date | Reference | Pat. No. | Pat. No. | Pat. No. |
|----------|----------|-------|--------|----------------|------|-----------|----------|----------|----------|
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11 30. Document ID: US 5356633 A

L2: Entry 30 of 32

File: USPT

Oct 18, 1994

US-PAT-NO: 5356633

DOCUMENT-IDENTIFIER: US 5356633 A

TITLE: Method of treatment of inflamed tissues

DATE-ISSUED: October 18, 1994

| NAME | CITY | STATE | ZIP CODE | COUNTRY |
|--------------------|---------------|-------|----------|---------|
| Woodle; Martin C. | Menlo Park | CA | | |
| Martin; Francis J. | San Francisco | CA | | |
| Huang; Shi K. | Castro Valley | CA | | |

US-CL-CURRENT: 424/450; 424/423, 424/426, 514/863, 514/886

[illegible]

| | | | | | |
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| | |
|---|------|
| Terms | Docu |
| (peg) same (polylact\$ or polyglycol\$ or polyvinyl) same phospholipid | |

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L3: Entry 85 of 89

File: USPT

July 6, 1993

US-PAT-NO: 5225212

DOCUMENT-IDENTIFIER: US 5225212 A

TITLE: Microreservoir liposome composition and method

DATE-ISSUED: July 6, 1993

INVENTOR INFORMATION:

| NAME | CITY | STATE | ZIP CODE | COUNTRY |
|-----------------------------|---------------|-------|----------|---------|
| Martin; Francis J. | San Francisco | CA | | |
| Woodle; Martin C. | Menlo Park | CA | | |
| Redemann; Carl | Walnut Creek | CA | | |
| Yau-Young; Annie | Palo Alto | CA | | |
| Radhakrishnan; Ramachandran | Fremont | CA | | |

US-CL-CURRENT: 424/450; 424/426, 424/78.31

CLAIMS:

It is claimed:

1. A liposome composition effective to extend, to at least 24 hours, the period of effective activity of a therapeutic compound which can be administered intravenously in a therapeutically effective amount and which is cleared in free form from the bloodstream with a halflife of less than about 4 hours, comprising

liposomes (i) composed of vesicle-forming lipids and between 1-20 mole percent of a vesicle-forming lipid derivatized with a polymer selected from the group consisting of polyethyleneglycol, polyacetic acid and polyglycolic acid, and (ii) having a selected mean particle diameter in the size range between about 0.1 to 0.4 microns, and

the compound in liposome-entrapped form,

for intravenous administration at a dose of the composition which contains an amount of the compound in liposome-entrapped form which is at least three times such therapeutically effective amount.

2. The composition of claim 1, wherein the hydrophilic polymer is polyethyleneglycol having a molecular weight between about 1,000-5,000 daltons.

3. The composition of claim 2, wherein the polymer is derivatized to a phospholipid.

4. The composition of claim 1, wherein the polymer is selected from the group consisting of polyacetic acid and polyglycolic acid.

5. A liposome composition effective to extend, to at least 48 hours, the period of therapeutic activity of a polypeptide which can be administered intravenously in a therapeutically effective amount, which is cleared in free form from the bloodstream with a half-life of less than about 4 hours, and whose therapeutically active blood concentration is in the picogram-nanogram/ml concentration range, comprising

liposomes (i) composed of vesicle-forming lipids and between 1-20 mole percent of a vesicle-forming lipid derivitized with a polymer selected from the group consisting of polyethyleneglycol, polyacetic acid and polyglycolic acid, and (ii) having a selected mean particle diameter in the size range between about 0.1 to 0.4 microns, and

the polypeptide in liposome-entrapped form,

for intravenous administration at a dose of the composition which contains an amount of the polypeptide liposome-entrapped form which is at least three times such therapeutically effective amount.

6. The composition of claim 5, wherein the hydrophilic polymer is polyethyleneglycol having a molecular weight between about 1,000-8,000 Daltons.

7. The composition of claim 5, wherein the polypeptide is a peptide hormone which is therapeutically active at a plasma concentration in the picogram/ml range, and the liposome composition is effective to release the hormone in a therapeutically effective dose for a period of at least five days after intravenous administration of the composition.

8. The composition of claim 7, wherein the peptide hormone is vasopressin.

9. The composition of claim 5, wherein the compound is a protein selected from the group consisting of superoxide dismutase, glucocerebrosidase, asparaginase, adenosine deaminase, interferons (alpha, beta, and gamma), interleukin (1,2,3,4,5,6,7), tissue necrosis factor (TNF-alpha, beta), colony stimulating factors (CSF (macrophage), G-CSF (granulocyte), GM-CSF (granulocyte, macrophage), TPA, prourokinase, and urokinase, HIV-1 vaccine, hepatitis B vaccine, malaria vaccine, and melanoma vaccine, erythropoietin (EPO), factor VIII, bone growth factor, fibroblast growth factor, nerve growth factor, platelet-derived growth factor, tumor growth factors (alpha, beta), somatomedin C (IGF-1), and a ribosome inhibitor protein.

10. The composition of claim 9, wherein the protein is macrophage colony stimulating factor.

11. A method of extending, to at least 24 hours, the period of effective activity of a therapeutic compound which can be administered intravenously in a therapeutically effective amount, and which has a half-life in the bloodstream in free form of less than about 4 hours, comprising

providing a liposome composition containing liposomes (i) composed of vesicle-forming lipids and between 1-20 mole percent of a vesicle-forming lipid derivitized with a polymer selected from the group consisting of

polyethyleneglycol, polyacetic acid and polyglycolic acid, and (ii) having a selected mean particle diameter in the size range between about 0.3 to 0.4 microns, and the compound at least about 70% in liposome-entrapped form, and

administering the liposome composition intravenously to a subject at a dose which contains an amount of the compound which is at least three times such therapeutically effective amount.

12. The method of claim 11, wherein the hydrophilic polymer is polyethyleneglycol having a molecular weight between about 1,000-5,000 daltons.

13. The method of claim 11, wherein the polymer is selected from the group consisting of polylactic acid and polyglycolic acid.

14. The method of claim 11, wherein the compound is a peptide hormone which is therapeutically active at a plasma concentration in the picogram-to nanogram/ml range, and said administering is effective to release the hormone in a therapeutically effective dose for a period of at least five days.

15. The method of claim 14, wherein the peptide hormone is vasopressin.

16. The method of claim 11, wherein the compound is a protein selected from the group consisting of superoxide dismutase, glucocerebrosidase, asparaginase, adenosine deaminase, interferons (alpha, beta, and gamma), interleukin (1,2,3,4,5,6,7), tissue necrosis factor (TNF - alpha, beta), colony stimulating factors (M-CSF (macrophage), G-CSF (granulocyte), GM-CSF (granulocyte, macrophage), TPA, prourokinase, and urokinase, HIV-3 vaccine, erythropoietin (EPO), factor VIII, bone growth factor, fibroblast growth factor, nerve growth factor, platelet-derived growth factor, tumor growth factors (alpha, beta), somatomedin C (IGF-1), and a ribosome inhibitor protein.

17. The method of claim 16, wherein the protein is macrophage colony stimulating factor.

18. A liposome composition effective to extend, to at least one week, the period of effective activity of a therapeutic compound which can be administered in a therapeutically effective amount, comprising

liposomes (i) composed of vesicle-forming lipids and between 1-20 mole percent of a vesicle-forming lipid derivitized with a polymer selected from the group consisting of polyethyleneglycol, polyacetic acid and polyglycolic acid, and (ii) having a selected mean particle diameter in the size range between about 0.3 to 0.4 microns, and

the compound in liposome-entrapped form,

for subcutaneous administration at a dose of the composition which contains an amount of the compound in liposome-entrapped form which is at least two times such therapeutically effective intravenously administered amount.

19. The composition of claim 18, wherein the compound is a polypeptide selected from the group consisting of superoxide dismutase, glucocerebrosidase, asparaginase, adenosine deaminase, interferons (alpha, beta, and gamma), interleukin (1,2,3,4,5,6,7), tissue necrosis factor (TNF - alpha, beta), colony stimulating factors (M-CSF (macrophage), G-CSF

(granulocyte), GM-CSF (granulocyte, macrophage), TPA, prourokinase, and urokinase, HIV-1 vaccine, hepatitis B vaccine, malaria vaccine, and melanoma vaccine, erythropoietin (EPO), factor VIII, bone growth factor, fibroblast growth factor, nerve growth factor, platelet-derived growth factor, tumor growth factors (alpha, beta), somatomedin C (IGF-1), and a ribosome inhibitor protein.

20. The composition of claim 19, wherein the polypeptide is vasopressin.

21. A method of extending, to at least one week, the period of effective activity of a therapeutic compound which can be administered in a therapeutically effective amount, comprising

providing a liposome composition containing liposomes (i) composed of vesicle-forming lipids and between 1-20 mole percent of a vesicle-forming lipid derivatized with a polymer selected from the group consisting of polyethyleneglycol, polyacetic acid and polyglycolic acid, and (ii) having a selected mean particle diameter in the size range between about 0.1 to 0.4 microns, and the compound at least about 70% in liposome-entrapped form, and

administering the composition subcutaneously to a subject at a dose which contains an amount of the compound in liposome-entrapped form which is at least ten times such therapeutically effective intravenously administered amount.

22. The method of claim 21, wherein the compound is a peptide homologue selected from the group consisting of superoxide dismutase, glucocerebrosidase, asparaginase, adenosine deaminase, interferons (alpha, beta, and gamma), interleukin (1,2,3,4,5,6,7), tissue necrosis factor (TNF-alpha, beta), colony stimulating factors (M-CSF (macrophage), G-CSF (granulocyte), GM-CSF (granulocyte, macrophage), TPA, prourokinase, and urokinase, HIV-1 vaccine, hepatitis B vaccine, malaria vaccine, and melanoma vaccine, erythropoietin (EPO), factor VIII, bone growth factor, fibroblast growth factor, nerve growth factor, platelet-derived growth factor, tumor growth factors (alpha, beta), somatomedin C (IGF-1), and a ribosome inhibitor protein.

23. The method of claim 22, wherein the polypeptide is vasopressin.

24. A liposome composition composed of vesicle-forming lipids and a vesicle-forming lipid derivatized with a hydrophilic polymer selected from the group consisting of polylactic acid and polyglycolic acid.

25. A lipid composition composed of a vesicle-forming lipid having a polar head group, and a polylactic acid moiety derivatized to said head group.

26. A lipid composition composed of a vesicle-forming lipid having a polar head group, and a polyglycolic acid moiety derivatized to said head group.

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L5: Entry 67 of 81

File: USPT

Dec 27, 1994

DOCUMENT IDENTIFIER: US 5376369 A

TITLE: Vaccine adjuvant

Brief Summary Text (52):

The term "surfactant" refers to non-toxic surface active agents capable of stabilizing the emulsion. There are a substantial number of emulsifying and suspending agents generally used in the pharmaceutical sciences. These include naturally derived materials such as gums, vegetable protein, alginates, cellulose derivatives, phospholipids (whether natural or synthetic), and the like. Certain polymers having a hydrophilic substituent on the polymer backbone have surfactant activity, for example, povidone, polyvinyl alcohol, and glycol ether-based compounds. Compounds derived from long chain fatty acids are a third substantial group of emulsifying and suspending agents usable in this invention. Though any of the foregoing surfactants can be used so long as they are non-toxic, glycol ether-based surfactants are preferred. Preferred surfactants are non-ionic. These include polyethylene glycols (especially PEG 200, 300, 400, 600 and 900), Span RTM., Arlacel RTM., Tween RTM., Myrj RTM., Brij RTM. (all available from ICI America Inc., Wilmington, Del.), polyoxyethylene, polyol fatty acid esters, polyoxyethylene ether, polyoxypropylene fatty ethers, bee's wax derivatives containing polyoxyethylene, polyoxyethylene lanolin derivatives, polyoxyethylene fatty glycerides, glycerol fatty acid esters or other polyoxyethylene acid alcohol or ether derivatives of long-chain fatty acids of 12-21 carbon atoms. The presently preferred surfactant is Tween RTM. 80 (otherwise known as polysorbate 80 or polyoxyethylene 20 sorbitan monooleate), although it should be understood that any of the above-mentioned surfactants would be suitable after lack of toxicity is demonstrated.

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L5: Entry 75 of 81

File: JPAB

Nov 20, 1985

DOCUMENT-IDENTIFIER: JP 60239417 A

TITLE: PREPARATION OF FREEZE-DRIED EMULSION DRUG

Abstract Text (2):

CONSTITUTION: A vehicle (e.g. saccharide, urea, etc.) and a water-soluble polymer selected from PVA, polyvinyl pyrrolidone, low-molecular weight gelatin, PEG, etc. are dissolved in the aqueous phase of an O/W-type emulsion. The obtained aqueous solution is mixed with an oil (e.g. soybean oil, linoleic acid, etc.) preferably at a ratio of (30~15):1, emulsified, and freeze-dried to obtain the objective drug preparation. The dissolution of the water-soluble polymer in the aqueous phase is effective to prevent the coagulation of the emulsion particles in the freeze-drying process, and accordingly, the obtained cake has excellent appearance and solubility and gives an emulsion having oil particle diameter of $\leq 2\sim 3\mu\text{m}$.

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